**2015-1862**

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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MEDTRONIC, INC. & MEDTRONIC VASCULAR, INC.,
*Appellants*

v.

LIFEPORT SCIENCES LLC,
*Appellee*

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*Appeal from the United States Patent & Trademark Office, Patent Trial and Appeal Board in Case No. IPR2014-00288*

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# APPELLEE'S PRINCIPAL BRIEF

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December 9, 2015

## CERTIFICATE OF INTEREST

Counsel for Appellee Lifeport Sciences, LLC certifies the following:

1. The full name of every party or amicus represented by me is: Lifeport Sciences, LLC.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: Lifeport Sciences, LLC.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: Acacia Research Group LLC and Acacia Research Corporation.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are: Cary Kappel, David Petroff, both of Davidson, Davidson & Kappel, LLC.

Date: December 9, 2015 */s/ Cary Kappel*

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## I. STATEMENT OF RELATED CASES

This appeal arises from the decision of the Patent Trial and Appeal Board ("PTAB") in the *Inter Partes* review of U.S. Patent No. 7,147,662 ("the '662 patent") in *Medtronic, Inc. v. Lifeport Sciences LLC*, No. IPR2014-00288 (P.T.A.B. Apr. 21, 2015) ("Final Written Decision"). This *inter partes* review was instituted in response to a petition filed by Medtronic Inc. and Medtronic Vascular Inc. (collectively, "Medtronic") against Patent Owner LifePort Sciences LLC ("LifePort"). No other appeal in or from the same *inter partes* review proceeding was previously before this or any other court.

The '662 patent is also the subject of a district court infringement case currently before the U.S. District Court for the District of Delaware: *LifePort Sciences LLC v. Medtronic Inc.*, No. 12-01793-GMS ("the Delaware Litigation"). The Delaware Litigation is stayed in its entirety pending the resolution of IPR2014-00288, through final appeal.

## II. JURISDICTIONAL STATEMENT

Medtronic's Principal Brief (DI-19) sets forth an accurate Jurisdictional Statement.

## III. COUNTER-STATEMENT OF ISSUES

Lifeport disagrees with Medtronic's argumentative characterization of the issues in this Appeal. Contrary to Medtronic's statement of issues, (i) the relied upon prior art does not "specifically show[] the identical and unchanging curvature for multiple embodiments of hooks on an endoprosthesis;" (ii) the "intrinsic evidence" does not "specifically disclose[] a curve that is permanently maintained *in vivo;*" and (iii) the PTAB did not require "that the prior art disclose heat treatment for the hooks." (DI-19, p. 3). Lifeport further disagrees that any alleged issue involves an "analytical error." (*Id*.)

Lifeport believes that the properly characterized issues in the Appeal are as follows:

(1) Whether the PTAB's finding that Medtronic failed to prove by a preponderance of the evidence that either White (PCT International Publication No. WO 00/18322) or Ostrovsky (U.S. Patent No. 6,447,530) teach a "permanent curve" is supported by substantial evidence.

(2) Whether the PTAB's finding that Medtronic failed to prove by a preponderance of the evidence that the combination of White (PCT International Publication No. WO 00/18322), in view of Ostrovsky (U.S.

Patent No. 6,447,530) teaches a "permanent curve" is supported by substantial evidence.

## IV. COUNTER-STATEMENT OF THE CASE

Lifeport disagrees with Medtronic's statement of the case, which mischaracterizes the '662 patent, its claims, the Final Written Decision of the PTAB, and the teachings of the prior art White and Ostrovsky references.

The '662 patent includes three independent claims (claims 1, 10 and 16) directed to "a mechanism for securing an endoprosthesis within a corporeal lumen," "a connector for fastening a device to corporeal tissues" and "an endoluminal prosthesis," respectively, as well as 13 dependent claims.

Medtronic filed a Petition for *Inter Partes* Review seeking to invalidate the claims of '662 patent on eight separate grounds. (A41-42). The PTAB instituted review of claims 1-5, 7-13, 15, and 16 based on four of those grounds (A142-143), and Lifeport opposed the Petition, arguing that the various prior art references lacked a *variety* of identified elements of the various claims and that Medtronic had further failed to establish sufficient motivation to combine the references in the manner asserted. (A146-148).

The PTAB held an Oral Hearing (A211-265) on the four instituted grounds and then issued a Final Written Decision (A1-34) finding that "Petitioner's have not proven, by a preponderance of the evidence, that any of claims 1-5, 7-13, 15, and 16 are unpatentable over the cited prior art." (A33). In its Principal Brief (DI-19), Medtronic only appeals two of the four rejected grounds. In particular, Medtronic appeals the PTAB ruling that "Petitioners have failed to establish that the combination of White and Ostrovsky teaches or suggests a 'permanent curve' and, thus, has not proven by a preponderance of evidence that the asserted combination renders claims 1- 4, 8 -12, and 16 obvious" (A23); and the PTAB ruling that "Petitioners have not proven by a preponderance of the evidence that the combination of White, Ostrovsky, and Lazarus renders claims 7 and 15 unpatentable under 35 U.S.C. § 103(a)." (A33).

Accordingly, the focus of this Appeal is the "permanent curve" limitations of independent claims 1, 10, and 16, which the PTAB construed as meaning "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." (A11). Medtronic does not challenge this construction on Appeal. (DI-19, p. 19, n. 4).

Although Medtronic argued during the *Inter Partes* Review that White disclosed engagement members having a permanent curve which does

not change curvature (i.e., maintains a fixed arc) regardless of what configuration the device is in (A8), Medtronic has abandoned that contention on Appeal, and does not contest the PTAB finding that White does not disclose a permanent curve.

Accordingly, the case on Appeal boils down to whether substantial evidence supports the PTAB's factual finding that Ostrovsky fails to disclose a permanent curve, and that the combination of White and Ostrovsky lacks a permanent curve.

Although Medtronic avers in its Statement of the Case that the "prior art combination (White and Ostrovsky) … unquestionably depicts and describes a hook on an endoprosthesis with a fixed, identical, unchanging arc," it in fact does not. (DI-19, p. 4). As noted above, Medtronic does not contest the PTAB finding of a lack of a permanent curve in White. Ostrovsky, in turn, consistently refers to the alleged "hooks" in all of its embodiments as *flexible* and *elastic* and made of the *same materials*, and the sole set of Figures depicting the hooks performance while deployed in the vein (Figures 22A-E) shows the hooks *changing curvature*. (A189-191, 249-251). The PTAB noted this, referencing the passages of Ostrovsky that describe the alleged "hooks" as elastic and flexible (A28-30), and concluding that "[a]lthough Ostrovsky discloses the use of '***elastic*** materials

including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys' . . . , Dr. Loomis fails to explain how the reference teaches the generation of a *permanent curve*." (A32)(Emphasis in original). Contrary to Medtronic's allegation, the PTAB carefully considered the teachings of Ostrovsky, including its express description of the alleged "hooks" as flexible and elastic, and found the disclosure insufficient to prove by a preponderance of the evidence that the alleged hooks have a permanent curve. The PTAB went on to examine the extrinsic evidence provided by Medtronic's expert Dr. Loomis, and found it insufficient and unreliable. (A32).

Further, Medtronic omits from its brief the fact that it did not argue in its Petition that a person of ordinary skill in the art would seek to substitute the alleged "hooks" of Ostrovsky for the flexible engagement members of White. Rather, they argued a person or ordinary skill in the art "would have been motivated to utilize the combined teachings of White and Ostrovsky to create a ***pointed end*** on ***White's*** engagement members," (A93)(Emphasis Added), and Medtronic ***now*** concedes that ***White's*** engagement members lack a permanent curve.

The PTAB's Final Written Decision is not only supported by substantial evidence, it is demonstrably correct.

# V. STATEMENT OF FACTS

## A. THE '662 PATENT AND ITS CLAIMS

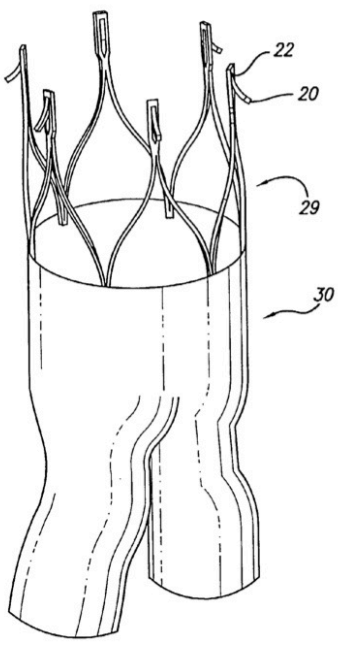
The '662 patent is entitled "Hook for Attaching to a Corporeal Lumen and Method of Manufacturing" and contains three independent claims (claims 1, 10 and 16). (A276-277). These claims are directed to "a mechanism for securing an endoprosthesis within a corporeal lumen," "a connector for fastening a device to corporeal tissues" and "an endoluminal prosthesis," respectively. Claims 1, 10 and 16 recite:

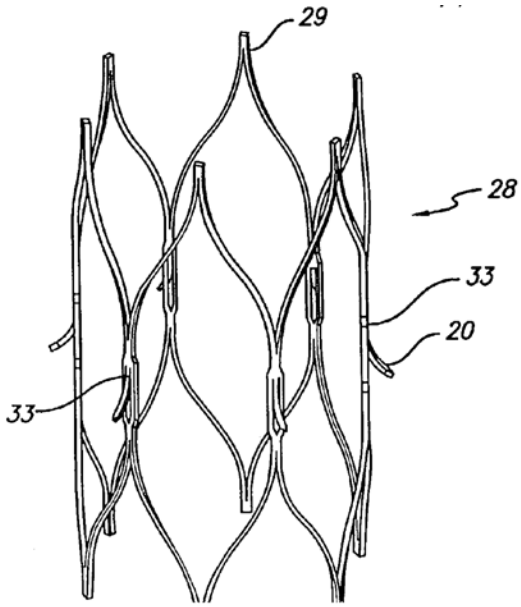
> 1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:
> a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;
> the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element; and
> the elongated member bent away from said frame element wherein the elongate member has a permanent curve.
>
> 10. A connector for fastening a device to corporeal tissues, said connector comprising:
> a substantially tubular body lacking concentrically overlapping structure;
> a hook having two sides and a point and being bounded by the tubular body;
> said sides and said point defined by narrow slits in the connector; and
> said hook having a permanent bend that forms a permanent curve.
>
> 16. An endoluminal prosthesis, comprising:

> a substantially tubular frame element, the frame element lacking concentrically overlapping structure; and
>
> at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein, wherein the at least one protrusion has a permanent curve the at least one protrusion being bounded by the frame element and the at least one protrusion having a pointed end.

Each claim requires that the claimed device comprises "a substantially tubular" element (i.e., a "frame element having a substantially tubular shape" in claim 1; a connector comprising "a substantially tubular body" in claim 10, and "a substantially tubular frame element" in claim 16), and requires that the substantially tubular element lacks "concentrically overlapping structure."

Such a "substantially tubular" frame element or body is shown in the attachment device 29 for graft 30 of Figure 5 and the endoprosthesis 28 of Figure 6:



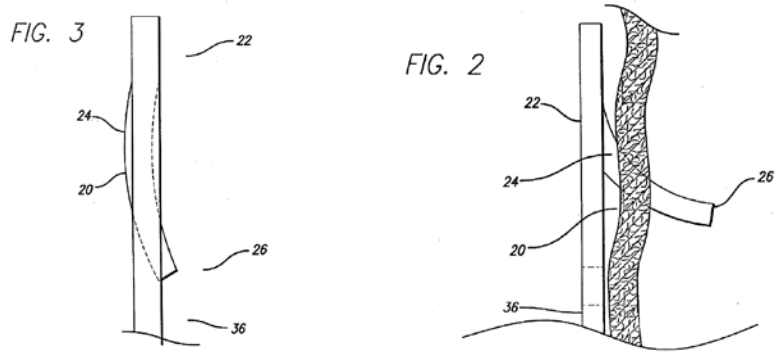

(A270, Figs. 5-6).

Claim 1 also recites "a frame element with incisions formed therein . . . the incisions forming an ***elongated member having a pointed end*** . . . the ***elongated member bent away*** from said frame element wherein the elongate member has ***a permanent curve***." Claim 10 is a bit different, reciting "a ***hook having*** two sides and ***a point*** . . . said hook having a ***permanent bend*** that forms a ***permanent curve***." And claim 16, in turn, recites "at least one ***protrusion*** cut out of said frame element having a ***resiliently flexible bend*** formed therein, wherein the at least one protrusion has a ***permanent curve*** . . . the at least one protrusion having a ***pointed end***." Accordingly, the enlongated member, the hook, and the protrusion each have a pointed end or point and a permanent curve. However, the protrusion of claim 16 also has a

"***resiliently flexible bend***", whereas the hook of claim 10 requires a "***permanent bend***" and the elongated member of claim 1 simply requires a "***bend***." (A276-277).

These features are described in various parts of the '662 patent. The '662 patent Abstract explains that in certain embodiments "[t]he hook is integrally formed with the framing structure and is preset into an outward bend, but is resiliently flexible so as to form a substantially straight profile when compressed" and that "[t]he hook is capable of impinging upon the corporeal lumen and thereby securing the prosthesis." (A266, Abst.).

The specification elaborates on this in connection with Figures 2 and 3:




In this regard, Figure 3 illustrates the hook 20 of Figure 2 in the compressed state (A274, 2:47-50[1]), and the specification explains:

> In the compressed configuration, as depicted in FIG. 3, the hook 20 is preferably compressed until the hook 20 is within the bounds or circumference of the frame 22. In this manner,

[1] Citations to column and line numbers use the convention col:line.

> the combination of the hook 20 and frame 22 forms a nearly flat profile. Since the hook 20 has been deformed into a ***preset bend***, the pointed end 26 may still extend a short distance out from the frame 22. Furthermore, due to ***the preset bend***, the elongated member 24 may extend a short distance out of the frame 22 in the opposite direction from the pointed end 26. This compression of the hook 20 provides a very narrow cross section which facilitates loading the device into a catheter for delivery.
> (A275, 3:26-38)(Emphasis added).

> With a ***permanently*** deformed hook 20, the hook 20 may still be compressed into alignment with the frame ***22 without losing the preset curve***. Thus, the hook 20 may be compressed into the frame for intraluminal low-profile delivery, and then deployed in the curved configuration by releasing.
> (A276, 6:7-11)(Emphasis added).

The specification further teaches that the curve in a hook "may be permanently set by heating." (A274, 2:21-24; A275, 5:60 to 6:4, A266, Abst.). The specification teaches that one set of conditions to permanently deform hook 20 and frame 22, when made of nitinol, is by "heating at 550°C for ten minutes." (A276, 6:3-4). The specification also contemplates that a "ceramic or plastic hook 20 and frame 22 combination might be formed in a bent configuration." (A276, 6:4-6, *also* A156, A233, lines 24-24).

## B. THE PRIOR ART AT ISSUE

### 1. WHITE (WO 00/18322)

White is entitled "Expanding Intraluminal Device," was published on April 6, 2000, and is accordingly prior art under 35 U.S.C. § 102(a).

White describes "an intraluminal device for use in the treatment of aneurysmal and stenotic disease." (A297, Abst.). The intraluminal device comprises a tubular body and at least one engagement member that is connected to or integral with a wall of the body. (A300, lines 8-15). Figures 6a and 6b of White illustrate "device 10 in its radially compressed and radially expanded states respectively" (A314, lines 34-35):

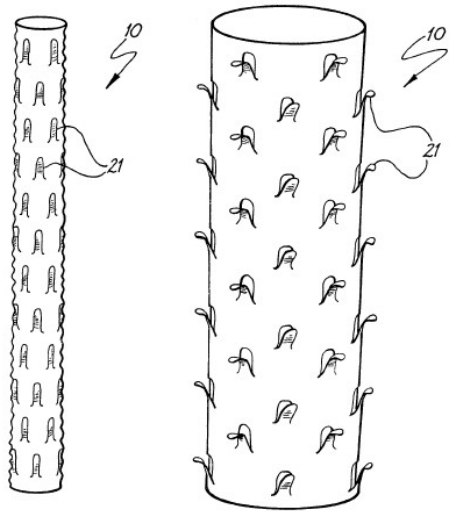



FIG. 6a FIG. 6b

Figures 6a and 6b show that **in the expanded state, engagement members 21 are *curved*, whereas, in the compressed state engagement**

**members 21 are *flat***. The engagement members are **rounded, *not* pointed**, a fact that Medtronic concedes. (A92).

White states that "the connection between the at least one engagement member and the body is such that it will allow the engagement member to occupy a first angular relationship with an adjacent part of the body when the body is radially compressed and a second and different angular relationship with the body when the body is radially expanded." (A300, lines 16-20). White states that, in the compressed state, the angular relationships of the engagement members to the wall of the device body "may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device." (A307, lines 27-33).

Although Medtronic argued during the *Inter Partes* Review that White disclosed engagement members having a permanent curve which does not change curvature (i.e., maintains a fixed arc) regardless of what configuration the device is in (A8, 25-28, 360), in its Appeal, Medtronic does not contest the PTAB's finding that White lacks a permanent curve (A25-28).

### 2. OSTROVSKY (U.S. Patent No. 6,447,530)

Ostrovsky is entitled "Atraumatic Anchoring and Disengagement Mechanism for Permanent Implant Device," and describes a recoverable thrombosis filter. (A278, Abst.).

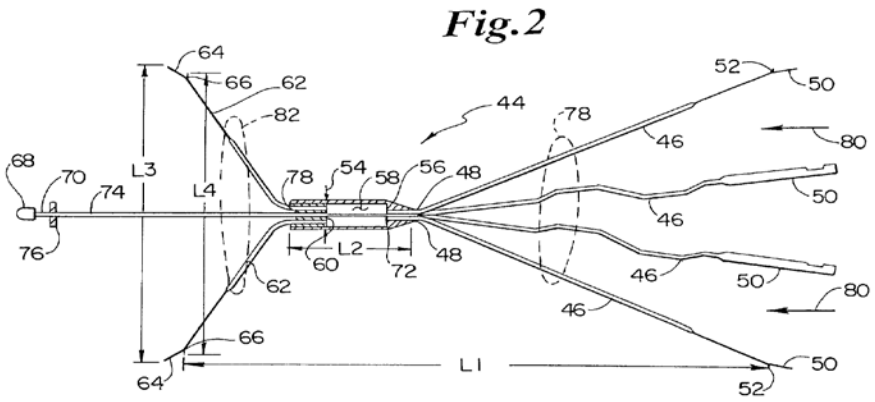
The filter "includes a plurality of thrombosis filtering elements that are shaped in a predetermined manner and which are joined at one end and are deployed about a longitudinal axis to form a generally conical structure." (A292, 3:8-10). Thus, Ostrovsky is a vena cava filter, not an endoprosthesis. (A388, ¶ 48, A391, ¶ 55).

In the Petition, Medtronic relies on Ostrovsky for disclosing engagement members which are pointed, as contrasted to White's rounded engagement members. (A92-99). In particular, the Petition cites to alleged "elongated member" 52 for claim 1 (A94), and alleged "hooks" or "protrusions" 52, 166 for claims 10 and 16 (A97, 99).

Component 166 is an end portion of flexible anchoring strut 162 of Figure 23-28. (A190, A295, 9:2-45). Flexible strut 162 is part of the embodiment of Figures 23-28, which is a further embodiment of flexible strut 62 with end 66 of the embodiments of Figures 2-14, and 15-17, 18-22. (A294, 8:57-62, A389-90, ¶¶ 50-53, A404 ¶ 88). Component 52 is

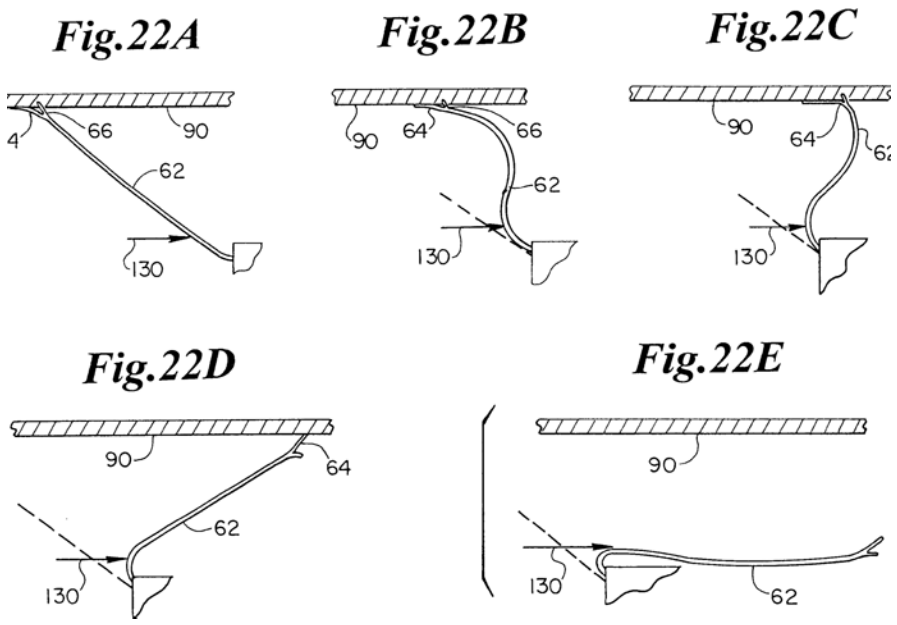
projection 52 of end member 50 of the embodiment of Figures 2-14. (A195, A405, ¶89).

Figure 2 shows filter 44 of Ostrovsky in a relaxed position (A292, 3:66-67):




The filter is described as having "[a] plurality of ***flexible*** anchoring struts 62 are mounted on mounting member 60 and project outwardly to wall engaging surfaces 64." (A293, 5:39-41)(Emphasis added). "Projections 66 function to position and hold the filter 44 in position when engaged to an inner vein wall." (A293, 5:41-42). It is further explained that "[t]he thickness [of end member 52] is selected for the desired ***flexibility***;" that "[a]n outward projection 52 is arranged for engaging the vein wall;" and that "[a] similar configuration is utilized for the anchoring elements." (A293, 6:1-4)(Emphasis added). Ostrovsky then notes that Figure 18 shows "another embodiment of a filter", and that "FIGS. 22A-22E illustrate the ***deflection*** and retraction of a ***flexible anchor*** member of the type used with

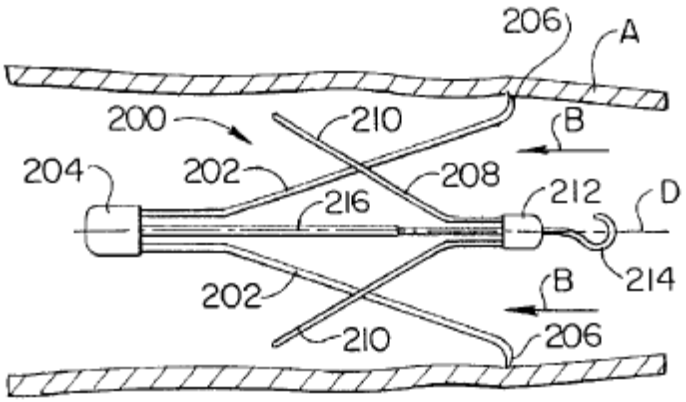
the filter of FIG. 18." (Emphasis added). As explained at col. 8, lines 30-55 (A294), these ***flexible*** anchoring struts 62 are illustrated as changing shape while deployed and secured in the vein:




Ostrovsky further explains that struts 162, 166 of Figures 23-28 are flexible and "will deform generally as shown in FIGS. 22A-22E)." (A295, 9:42-43).

In its IPR Reply (A360-361) and in the Appeal Brief (DI-19), Medtronic points to the end 206 of struts 202 of Figures 29-35 of Ostrovsky:

*Fig. 29*




However, like flexible struts 62, 162 of Figures 2-28, struts 202 are described as "flexible struts 202" (A295, 9:62, A389-90, ¶¶ 50-53, A404 ¶ 88), and Ostrovsky states that "struts 202 or loops 210 may be formed from nitinol, stainless steel or other biocompatible materials" and that the struts 202 may be made of the same materials as the other emobodiments. (A295, 10:9-14). Ostrovsky further states that: "[t]he various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys." (A295-296, 10:65-11:1).

Figures 30-35 illustrate the ***removal*** of the filter of Figure 29. Unlike Figures 22A-22E, Figures 29-35 are not illustrations of the manner in which the flexible struts deform while secured to the vein. There is no suggestion

whatsoever in Ostrovsky that the flexible struts 202, 206 are less flexible than the flexible struts 62, 66 of Figure 22, or the flexible struts 162, 166 of Figures 23-28. (A248-251, A389-390).

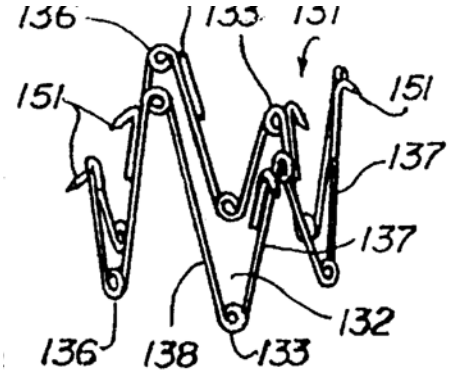
### 3. LAZARUS (U.S. Patent No. 5,562,728)

Lazarus was relied upon by Medtronic in support of its allegation that dependent claims 7 and 15 were obvious over the combination of White, Ostrovsky and Lazarus. Dependent claim 7 requires that the pointed end of the elongated member includes "at least one barb" and dependent claim 15 requires that the point of the hook has an arrowhead configuration. In the Petition, Medtronic alleged that Lazarus showed such a barb or arrowhead configuration, and that a person of ordinary skill in the art would have been motivated to further modify the alleged hooks of White (as modified by Ostrovsky) to have a barb or arrowhead configuration. (A100-101).

Lazarus describes an "[e]ndovascular grafting system having a capsule catheter comprising a flexible elongate tubular member having proximal and distal extremities and a capsule mounted on the distal extremity of the tubular member."

"Hook-like elements 151 are provided on the apices lying in planes 141 and 142 and are secured to the vees 132 in the vicinity of the apices by

suitable means such as welding." (A339, 8:56-59). Alternative hook-like elements include body 163 with barb 162 of Figure 12 (A340, 10:25-29) and the body 167 with conical tip 168 and spring-like ribbons 169 of Figure 13 (A340, 10:36-38):



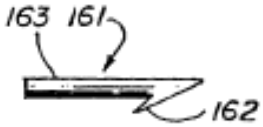




Fig. 12

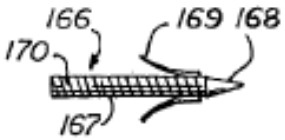



Fig. 13

Body 163 and body 167 are described as having "a diameter." (A340, 10:30-34, 37-38). Accordingly, these elements are round, rather than flat. Further, they are welded to the filter, not formed from slits in a tubular element like the flat protrusions of White.

As the PTAB noted in the Written Decision, Medtronic did not assert that Lazarus disclosed the "permanent curve" limitation. (A22-23, 32-33). Rather, Medronic alleged that the permanent curve was provided by White and Ostrovsky.

## C. THE PTAB PROCEEDINGS

### 1. THE PETITIONER'S EVIDENCE

Medtronic filed a Petition for *Inter Partes* Review seeking to invalidate the claims of the '662 patent on eight separate grounds (A41-42), heavily relying on the Declaration of its expert Dr. Loomis. The PTAB instituted review of claims 1-5, 7-13, 15, and 16 based on four grounds (A142-143), corresponding to Grounds 1, 2, 7, and 8 of the Petition.

From the start, the PTAB had concerns with the reliability of Dr. Loomis' testimony, rejecting his conclusions on four separate occasions. In particular, in the Institution Decision, the PTAB found that Dr. Loomis' opinion regarding claim 4 in Ground 1 did "not explain adequately why" the prior art would act as he claimed (A119-120); that his opinion regarding claims 6 and 14 in Ground 1 lacked "sufficient analysis" and was "insufficient" (A121); and that his opinion regarding Ground 3 and Ground 4 did "not explain adequately why" the references would have been combined (A131-A132, A134).

As set forth above, the Final Written Decision of the PTAB rejected all four of the instituted grounds, and herein Medtronic only appeals the rejection of Ground 7 (White in view of Ostrovsky) and Ground 8 (White in

view of Ostrovsky and Lazarus). Accordingly we will focus on Medtronic's evidence with respect to the appealed Grounds 7 and 8.

In the Petition, in its Reply, and at Oral Argument, it was Medtronic's position that White disclosed each and every limitation of independent claims 1, 10, and 16, except that the protrusions of White (which allegedly correspond to the claimed elongated members, hook, and protrusion) lack a point or pointed end. (A92, A137, A227 (lines 7-8), A229 (lines 4-5), A360).

Medtronic argued that Ostrovsky disclosed pointed members in the form of pointed struts, and that "a person of ordinary skill dealing with the propensity of an intraluminal device to migrate from the desired location would have been motivated to utilize the combined teachings of White and Ostrovsky ***to create a pointed end on White's engagement members ….***" (A92-93)(Emphasis added).

Nowhere in the record has Medtronic articulated any motivation for one of ordinary skill in the art to make any modification to the engagement members of White other than to make their ends pointed, rather than rounded. There is no allegation in the record that Ostrovsky would lead a person or ordinary skill in the art to modify the materials used for the

protrusions of White, their thicknesses, or any other characteristic other than making the rounded ends pointed.

With regard to the "permanent curve" limitation, Medtronic proposed the following construction in its Petition "a preset curve that maintains a permanent curve regardless of what configuration the device is in" (A53), which it supported with the testimony of Dr. Loomis. The PTAB adopted this construction in its Institution Decision (A114), also citing Dr. Loomis, and, in its Patent Owner's Response, Lifeport agreed (A157). Dr. Loomis then submitted a second declaration in which he testified to exactly what that construction meant:

> In paragraph 70 and 74 of my original declaration, I stated that Lefebvre disclosed a tooth that "maintains a permanent curve regardless of what the configuration of the device is in." In other words, ***the curve is the same*** whether the device is in the compressed configuration for insertion into the lumen or in the expanded configuration after deployment. (A429)(Emphasis added).

At Oral Argument, Medtronic offered what can only be considered an entirely new construction, that the term "permanent curve" simply means that "it always has a curve in both the compressed and uncompressed configuration" and thus encompasses a curve that *changes shape* during use. (A219, lines 4-12). Medtronic contended that it was only Lifeport that more narrowly construed the term to require that the same curve is maintained

regardless of the configuration the device was in. As noted above, the PTAB adopted this narrower construction, which it slightly rephrased as "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." (A11). In any event, at the Oral Hearing, Medtronic asserted that both White and Ostrovsky provided a permanent curve in accordance with this narrower construction.

### 2. THE PATENT OWNER'S EVIDENCE

In its Patent Owner Response, Lifeport submitted a Declaration of its expert Ellen Golds, and argued that neither White nor Ostrovsky disclosed a permanent curve.

With regard to White, Lifeport pointed out that the curves in the engagement members 21 are not "permanent" as recited in claims 1, 10 and 16 of the '662 patent, because the curves are not maintained in the compressed state. (A185, A400-404, ¶¶ 80-87). Lifeport further argued that there was no disclosure in White to suggest engagement members having a permanent curve, and that in fact White stressed the changing curvature of the protrusions, describing them as having shape "memory" (A186-189). Lifeport also pointed out that the protrusions of White were rounded, and that White expressed concern that even these rounded protrusions might perforate a vessel wall. (A192-193).

With regard to Ostrovsky, Lifeport showed that in each and every embodiment of Ostrovsky, the alleged pointed hooks/members were described as flexible: flexible struts (62, 66, 162, 166, 206, 202) and protrusions (50,52) with "flexibility", that Figures 22A-E of Ostrovsky were expressly directed to showing how these flexible struts reacted while deployed in the vein during use, and that these Figures expressly showed that the flexible struts changed curvature while secured to the vein. (A189-192, A195, A249-50). Lifeport further pointed out that in arguing that Ostrovsky had the "resiliently flexible bend" of claim 16 Petitioner's expert, Dr. Loomis noted the "frame element (166) [is] made of 'flexible' and 'resilient' material" and that "such material is that it has a resiliently flexible bend." (A190, A195). And of course, element 166 is the end 166 of flexible strut 162. Lifeport showed that all of the flexible struts (62, 66, 162, 166, 206, 202) and the protrusions (50, 52) are described as being made of the same materials. (A250). As Ellen Golds testified, nothing in Ostrovsky indicates that any of the alleged pointed engagement members have a permanent curve. (A388-391, 404-405, ¶¶48-54, 88-90).

Lifeport further argued that nowhere in the record has Medtronic articulated any motivation for one of ordinary skill in the art to make any modification to the engagement members of White other than to make their

ends pointed, rather than rounded. (A189-190). There is no allegation in the record that Ostrovsky would lead a person of ordinary skill in the art to modify the materials used for the protrusions of White, their thicknesses, or any other characteristic other than making the rounded ends pointed. (A248, A251-252).

Lifeport further argued that White and Ostrovsky were not properly combinable. Lifeport cited to the testimony of Ellen Golds that Ostrovsky was directed to a vena cava filter while White was directed to a stent graft, and that "this is a significant distinction, and a person or ordinary skill in the art would be skeptical when transferring features of one to the other." (A192). Lifeport further argued that a person of ordinary skill in the art at the time of the invention would not have modified the rounded protrusions of White to be pointed because White already expressed concern that its rounded protrusions may "perforate the vessel wall." (A190-194).

### 3. THE FINAL WRITTEN DECISION

After considering all of the evidence, and after conducting an oral hearing, the PTAB issued a detailed thirty-three page Final Written Decision denying all four instituted grounds and finding that "Petitioner's have not proven, by a preponderance of the evidence, than any of claims 1-5, 7-13, 15, and 16 are unpatentable over the cited prior art." (A33).

In rendering its decision, the PTAB carefully considered the evidence submitted by the parties and their respective experts. In the Final Written Decision, the PTAB continued to be troubled by the testimony of Medtronic's expert Dr. Loomis, stating with regard to his analysis of Lefebvre (Grounds 1 and 2) "we find his analysis speculative and accord it little weight." (A19); and further finding "a lack of rigor and reliability in Dr. Loomis's analysis" (A20). The PTAB further stated that "[o]ur concerns are heightened by Dr. Loomis's apparent lack of expertise in the relevant field," (A20) and finding that his credentials "are not well matched to the mechanical and structural issues of the present matter" (A21). In fact, the PTAB noted that Dr. Loomis "does not possess the educational background required by his own definition" of a person of ordinary skill in the art at the time of the invention. (A21, n. 13).

The PTAB's concerns with the lack of thoroughness in Dr. Loomis' analysis permeate the entire written decision. The PTAB found that Dr. Loomis did not "adequately explain" his analysis of White, in fact finding "[a]t best, Dr. Loomis identifies changes in the shape of White's engagement members in response to temperature or compressive forces" and that "[o]n their face, such changes are incompatible with a permanent curve." (A27-28).

The PTAB found that "[b]y contrast, we find that Lifeport's expert, Ms. Golds, has substantial and highly relevant experience in the design, development, manufacture, and testing of vascular implants, including vena cava filters and self-expanding Nitinol stents." (A21). The PTAB went on to state "[a]ccordingly, we credit Ms. Gold's testimony that '[n]othing in the disclosure of White indicates that the engagement members 21 have a permanent curve.'" (A28).

With regard to Ostrovsky, the PTAB first considered the reference itself, which described the relied upon struts as "flexible anchoring strut[s] 202" (A30), discloses the use of "elastic materials" (A32), taught that "'[t]he thickness [of engaging end 50] is selected for the desired flexibility'" (A30); and taught that "'[a] similar configuration is utilized for the anchoring elements,' such as anchoring struts 62." (A30).

After recounting all of these descriptions of the flexibility and elasticity of the relied upon struts of Ostrovsky, the PTAB turned to Dr. Loomis' testimony seeking an explanation of how Medtronic could establish that these struts nevertheless had a permanent curve. The PTAB once again found Dr. Loomis' analysis inadequate, finding that even though Ostrovsky teaches the use of "elastic materials", Dr. Loomis "fails to explain how the references" nevertheless teach a permanent curve. (A32). The PTAB noted

that Ostrovsky does not describe the "elastic" materials as being treated in any manner that would cause them to have a permanent curve (e.g., by heating under specified conditions) (A32); that the relied upon struts 202 of Ostrovsky are expressly described as "flexible anchoring strut[s]" (A30), made of "elastic materials" (A32); and that Dr. Loomis failed "to address the forces acting on any part of an Ostrovsky device alleged to teach or disclose a permanent curve." (A32). In short, Dr. Loomis provided insufficient evidence to support his contention that the alleged components, which are expressly described as *flexible* and made of an *elastic* material, nevertheless have a permanent curve. The PTAB concluded "[a]ccordingly, we find the evidence of record insufficient to demonstrate that Ostrovsky maintains a permanent curve as defined herein. (A32).

## VI. SUMMARY OF ARGUMENT

The PTAB carefully examined the submissions of the parties, conducted a full oral hearing, issued a detailed written decision which considered and weighed all of the intrinsic and extrinsic evidence submitted, and found that Medtronic had not met its burden in establishing invalidity of any claim of the '662 patent on any of the four instituted grounds.

Medtronic only appeals two of the four rejected grounds: (i) obviousness of claims 1-4, 8-12, and 16 in view of the combination of White and Ostrovsky; and (ii) obviousness of claims 7 and 15 in view of the combination of White, Ostrovsky, and Lazarus.

Moreover, Medtronic's appeal focuses *solely* on whether Ostrovsky meets the "permanent curve" limitation of the claims at issue.

Medtronic does not contest the PTAB's construction of the term "permanent curve" as "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." Nor does Medtronic contest the PTAB's finding that White does not disclose a permanent curve as construed by the PTAB. Further, Medtronic makes no argument whatsoever about Lazarus.

Accordingly, Medtronic's appeal rests solely on the issue of whether the relied upon components of Ostrovsky: struts 62, 66, 162, 166, 202, 206 and projection 52, provide a permanent curve. The PTAB carefully considered the teachings of Ostrovsky and properly found that nothing in Ostrovsky established that any of these components have a permanent curve. To the contrary, the PTAB found that these components were all described as ***flexible and made of elastic materials***, and that Medtronic had failed to

come forward with sufficient evidence to establish that these components nevertheless somehow had a ***permanent curve***.

After examining the intrinsic evidence and finding no disclosure of a permanent curve, the PTAB carefully considered the evidence submitted by Medtronic's expert Dr. Loomis, and found it inadequate and unreliable. Contrary to Medtronic's allegation in its Principal Brief, the PTAB did not *require* extrinsic evidence, nor did it *require* that Medtronic provide evidence of heat treatment or methods of manufacture, or the analysis of forces. Rather, the PTAB found that the *intrinsic* evidence was insufficient to show that the flexible components made of elastic materials nevertheless had a permanent curve, and that the extrinsic evidence submitted by Dr. Loomis was insufficient. In noting this insufficiency, the PTAB recounted *examples* the *type*s of extrinsic evidence *that Dr. Loomis might have provided but did not*, such as evidence that flexible components had been treated or manufactured in some manner that they would have a permanent curve; or evidence that the forces applied during use would not deform the flexible components.

Substantial evidence supports the PTAB's findings. In fact, the PTAB's findings are demonstrably correct.

## VII. ARGUMENT

### A. STANDARD OF REVIEW

The PTAB's factual findings are reviewed under the substantial evidence standard: "[W]e set aside factual findings that are unsupported by substantial evidence." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363-64 (Fed. Cir. 2006); *In re Cuozzo Speed Technologies,* 793 F.3d 1268, 1280 (Fed. Cir. 2015) ("We review the Board's factual findings for substantial evidence…"); *Rambus Inc. v. Rea,* 731 F.3d 1248, 1251-52 (Fed. Cir. 2013) (*citing In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000)). "An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions." *Falko-Gunter*, 448 F.3d at 1364.

Medtronic asserts that the PTAB made "analytical" errors that are not entitled to deference. As set forth below, there were no "analytical" errors. The proper standard is one of substantial evidence.

### B. THERE WERE NO ANALYTICAL ERRORS

Medtronic makes three arguments in support of its contention that the substantial evidence standard does not apply. None has merit.

First, Medtronic argues that the "PTAB committed an analytical error, when it incorrectly determined that White and Ostrovsky do not disclose a

permanent curve." (DI-19, Argument Section II). However, the findings of which Medtronic complains are purely factual determinations of the PTAB. First, Medtronic does not even argue in its Principal Brief that White discloses a permanent curve. Second, what the PTAB properly found was that the struts (62, 66, 162,166, 202, 206) and protrusions (50, 52) of Ostrovsky were expressly described as flexible and made of elastic materials. Further, the Figures in Ostrovsky that were directed to how the struts reacted during deployment (Figure 22A-E) expressly showed the struts *changing* curvature. In view of this intrinsic record, the PTAB looked to the extrinsic evidence to see if Medtronic had established that nevertheless the struts had a permanent curve, and the PTAB rejected Medtronic's extrinsic evidence as inadequate.

Second, Medtronic alleges that "the PTAB committed legal error by effectively requiring that the prior art disclose heat treatment for the hooks of an endoprosthesis even though (a) the construed claim does not include a limitation on how a 'permanent curve' is created, and (b) the prior art combination specifically discloses one of the materials that LifePort itself contends can be used to make a curve 'permanent.'" (DI-19, p. 3). Again, this misstates the record.

The PTAB did not in any way "require" that the prior art Ostrovsky patent disclose heat treatments. Rather, the PTAB found that nothing in the intrinsic record established that the struts (62, 66, 162,166, 202, 206) and protrusions (50, 52) -- which were expressly described as flexible and made of elastic materials -- had a permanent curve. As part of this analysis, the PTAB simply noted that in providing extrinsic evidence, Dr. Loomis did not provide any reason to conclude that any part of these flexible and elastic components had a permanent curve. The PTAB cited "heat treatment" as *an example* of a *type* of such extrinsic evidence that *might* have been proffered *but was not* because the '662 patent expressly describes *nitinol* as being flexible *unless* it is heat treated in specific manner.

Medtronic's third argument is that Ostrovsky mentions that "other biocompatible materials" besides nitinol and stainless steel can be used and that plastic is a biocompatible material. This position lacks any merit. First, *nowhere in the record before the PTAB did Medtronic make such an argument*. Accordingly, the PTAB could not commit an "analytical error" in not considering an argument that was never made. Second, White and Ostrovsky teach that the components at issue are *flexible* and *elastic*, and accordingly, it is *flexible and elastic* biocompatible materials that are taught by Ostrovsky, and therefore the reference to biocompatible materials and

plastics in no way undermines the PTAB finding that Ostrovsky lacks a permanent curve.

None of Medtronic's arguments justify a departure from the substantial evidence standard.

### C. THE "SUBSTANTIAL EVIDENCED STANDARD"

"A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding." *K/S Himpp v. Hear-Wear Technologies, LLC*, 751 F.3d 1362, 1364 (Fed. Cir. 2014) (*citing Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). This Court has noted that the "substantial evidence" standard of review for fact findings made by the PTAB makes the Appellant's burden on appeal "a challenging one." *Leo Pharm. Products, Ltd. v. Rea*, 726 F.3d 1346, 1348 (Fed. Cir. 2013).

At trial, the burden of proving unpatentability rested with Medtronic. *See* 35 U.S.C. § 316(e). On appeal, Medtronic bears an even more substantial burden. For Medtronic to prevail on appeal, it "must not only show the existence of error, but also show that the error was in fact harmful because it affected the decision below." *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004). The "burden of showing that an error is harmful normally falls upon the party attacking the agency's determination," which in this case is Medtronic. *See Shinseki v. Sanders*, 556 U.S. 396, 409 (2009). Even if

Medtronic identifies some error in the Board's decision, this Court may nonetheless affirm the Board's decision "on any ground that is supported by the record." *Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013).

### D. NEITHER PARTY CONTESTS THE PTAB'S CONSTRUCTION OF THE "PERMANENT CURVE" LIMITATION

The PTAB construed the term "permanent curve" as meaning "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." (A11). Medtronic does not challenge this construction on Appeal. (DI-19, p. 19, n. 4). Nor does Lifeport.

Accordingly, the propriety of the claim construction is not an issue on appeal. *See Litecubes, LLC v. N. Light Prods.*, 523 F.3d 1353, 1371 (Fed. Cir. 2008)("The parties do not contest the propriety of the district court's claim construction. Therefore, the only issue is whether substantial evidence supports the jury's factual finding that GlowProducts' cubes met the contested claim limitations"); *Catalina Lighting v. Lamps Plus*, 295 F.3d 1277, 1285 (Fed. Cir. 2002)("On appeal, Catalina . . . does not contest the court's claim construction. Thus, our focus is on the second step of the infringement analysis").

### E. MEDTRONIC DOES NOT APPEAL THE PTAB FINDING THAT MEDTRONIC FAILED TO SHOW THAT WHITE TEACHES A PERMANENT CURVE

Although Medtronic somewhat cryptically refers to the "White-Ostrovsky combination" as disclosing a permanent curve (DI-19, pp. 5, 22), nowhere in its Principal Brief does Medtronic allege that White discloses a permanent curve.

Nor could it reasonably do so for the reasons set forth in the Final Written Decision. (A23-28). As explained by the PTAB, White describes a device which has curved engagement members in the expanded state (Figure 6b), and "describes that, in the compressed state, the angular relationships of the engagement members to the wall of the device body 'may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device body.'" (A24). An engagement member that is curved in an expanded state and "flat" in a compressed state (Figs 6a,b) clearly lacks a permanent curve. With regard to the embodiment where in the compress state the "engagement members may project inwardly," for the reasons set forth by the PTAB (A25-28), "'[n]othing in the disclosure of White indicates that the engagement members 21 have a permanent curve.'" (A28). Indeed, in its description of White on appeal, Medtronic states "[i]n

such embodiments, the engagement members are never 'flat'; they maintain *some* curvature in both configurations." (DI-19, p. 14)(Emphasis added). Nowhere in its Principal Brief does Medtronic allege that White provides a permanent curve.

### F. THE PTAB PROPERLY FOUND THAT MEDTRONIC FAILED TO SHOW THAT OVSTROVSKY TEACHES A PERMANENT CURVE AS CLAIMED

Substantial evidence supports the PTAB's finding that Ostrovsky does not disclose a permanent curve.

#### 1. NONE OF THE COMPONENTS OF OSTROVSKY ALLEGED TO BE THE CLAIMED ELONGATED MEMBERS (CLAIM 1), HOOK (CLAIM 10) OR PROTRUSIONS (CLAIM 16) HAVE A PERMANENT CURVE

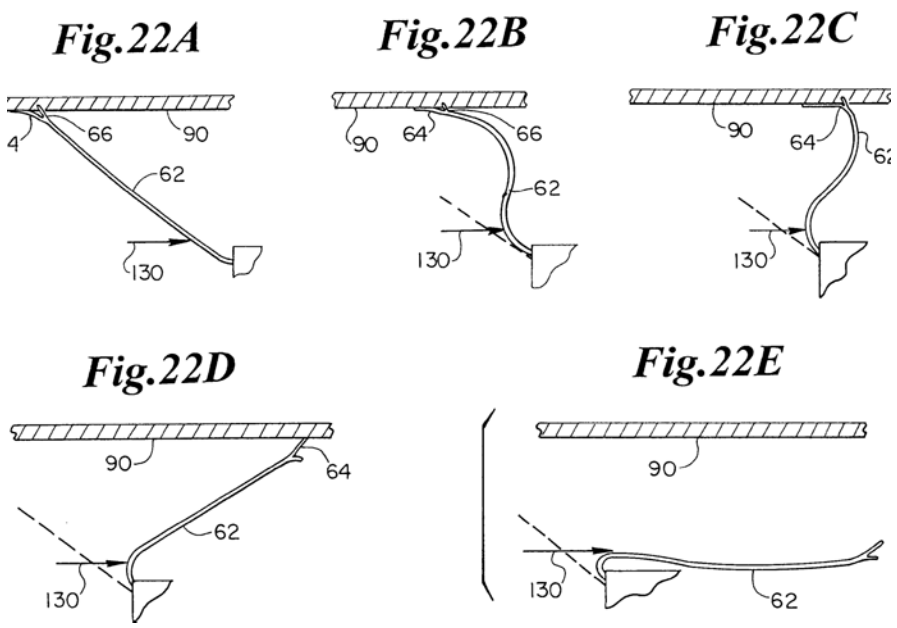
In its Petition alleging invalidity based on the combination of White and Ostrovsky (Ground 7, A90-99) and White, Ostrovsky and Lazarus (Ground 8, A100-102), Medtronic cites to the alleged "protrusions" 52 of Figure 3 of Ostrovsky as disclosing the elongated member of claim 1 having a permanent curve (A94), the alleged "hooks" or "protrusions" 52, 166 of Figures 3 and 24 for the "hook" of claim 10 having a permanent curve (A97) and the protrusion of claim 16 having a permanent curve (A99). In its Reply Brief, Medtronic switched tactics and instead relied upon the flexible struts

206 of Figures 33-35. However, none of the alleged "hooks" or "protrusions" 52, 162, 166, 202, or 206 are described as having a permanent curve. To the contrary, they are consistently referred to as "flexible", made of "elastic materials" and shown to deform and change curvature while deployed in a vein.

Substantial evidence supports the PTAB's finding that Ostrovsky does not disclose a permanent curve. In fact, the PTAB's findings are demonstrably correct. The PTAB correctly found that the "'[t]he various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys;'" (A28) that "'[t]he selection of materials will also determine the flexibility and resiliency of the various members'" (A28); that the struts 62 and 202 are "flexible" struts (A29, A30); that "'[t]he thickness [of engaging end 50] is selected for the desired flexibility.'" (A30), and that "'[a] similar configuration is utilized for the anchoring elements,' such as anchoring struts 62 shown in Figure 2." (A30). Accordingly, the PTAB found that all of the components in Ostrovsky that were alleged to correspond to the claimed hook or elongated member having a permanent curve where instead expressly described as *flexible* and made of *elastic* materials.

These findings are demonstrably correct. Ostrovsky describes several embodiments of a filter: filters with flexible struts 62, 66 and protrusions 52 (Figures 2-22); filters with flexible struts 162, 166 (Figures 23-27) and filters with flexible struts 202, 206 (Figures 29-35).

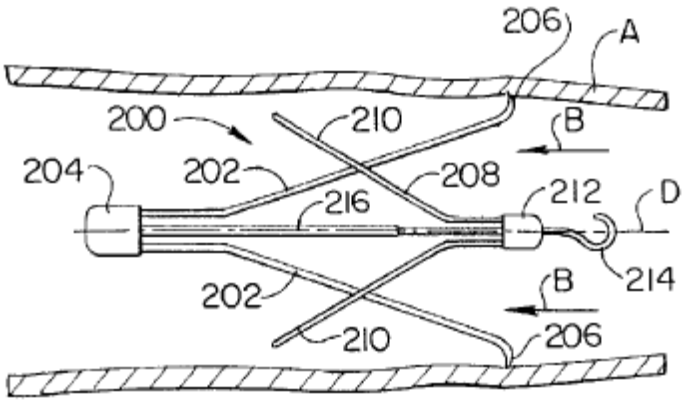
The filters of Figures 2-22 are described as having "[a] plurality of ***flexible*** anchoring struts 62 are mounted on mounting member 60 and project outwardly to wall engaging surfaces 64." (A293, 5:39-41)(Emphasis added). "Projections 66 function to position and hold the filter 44 in position when engaged to an inner vein wall." (A293, 5:41-42). It is further explained that "[t]he thickness [of end member 52] is selected for the desired ***flexibility***;" that "[a]n outward projection 52 is arranged for engaging the vein wall;" and that "[a] similar configuration is utilized for the anchoring elements." (A293, 6:1-4)(Emphasis added). Ostrovsky then notes that Figure 18 shows "another embodiment of a filter", and that "FIGS. 22A-22E illustrate the *deflection* and retraction of a ***flexible anchor*** member of the type used with the filter of FIG. 18." (A292, 4:41-43)(Emphasis added). As explained at col. 8, lines 30-55 (A294), these ***flexible*** anchors 62 are illustrated as changing shape while deployed and secured in the vein:




Ostrovsky further states that struts 162, 166 of Figures 23-28 are ***flexible*** and "will deform generally as shown in FIGS. 22A-22E)" (A295, 9:42-43). Indeed, Medtronic and its expert expressly allege in the Petition that "Ostrovsky discloses a frame element (166) made of "flexible" and "resilient" material." (A99).

In its IPR Reply (A360-361) and in its Principal Brief (DI-19), Medtronic has switched tactics, and instead pointed to the end 206 of struts 202 of Figures 29-35 of Ostrovsky:

*Fig. 29*




However, like flexible struts 62, 162 of Figures 2-28, struts 202 are described as "flexible struts 202" (A295, 9:62). Ostrovsky teaches that "struts 202 . . . may be formed from nitinol, stainless steel or other biocompatible materials;" and that the struts 202 may be made of the same materials as the other embodiments. (A295, 10:9-14). Ostrovsky further states that: "[t]he various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys." (A295-296, 10:65-11:1).

Figures 30-35 illustrate the ***removal*** of the filter of Figure 29. Unlike Figures 22A-22E, Figures 29-35 are not illustrations of the manner in which the flexible struts deform while secured to the vein. There is no suggestion whatsoever in Ostrovsky that the flexible struts 202, 206 are less flexible

than the flexible struts 62, 66 of Figure 22, or the flexible struts 162, 166 of Figures 23-28. (A248-251, A389-390). There is nothing in Ostrovsky that suggests that the flexible struts 202, 206 will not change curvature and deform while secured in the vein just as illustrated in Figures 22A-E. Accordingly, the PTAB properly found that nothing in Ostrovsky teaches that any of the relied upon components 52, 62, 66, 162, 166, 202, or 206 have a permanent curve as claimed.

Having exhausted the intrinsic record, the PTAB properly went on to consider and weigh the extrinsic evidence proffered by Medtronic's expert Dr. Loomis.

Initially, it must be noted that the PTAB found Dr. Loomis' testimony to be generally unreliable, stating with regard to his analysis of Lefebvre (Grounds 1 and 2) "we find his analysis speculative and accord it little weight" (A19); and further finding "a lack of rigor and reliability in Dr. Loomis's analysis" (A20). It is well with the discretion of the PTAB to give each item of evidence the weight it feels appropriate. *See Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003). The PTAB further stated that "[o]ur concerns are heightened by Dr. Loomis's apparent lack of expertise in the relevant field," (A20) and finding that his credentials "are not well matched to the mechanical and structural issues of the present

matter" (A21). *See, e.g., Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1364 (Fed. Cir. 2008) (a witness not qualified in the pertinent art may not testify as an expert on obviousness, anticipation or any of the underlying technical questions). In fact, the PTAB noted that Dr. Loomis "does not possess the educational background required by his own definition" of a person of ordinary skill in the art at the time of the invention. (A21, n. 13). *See General Electric Co. v. Wilkins*, 750 F.3d 1324, 1329 (Fed. Cir. 2014) ("Credibility determinations are entitled to strong deference"). The PTAB's concerns with the lack of thoroughness in Dr. Loomis' analysis permeate the entire written decision. The PTAB found that Dr. Loomis did not "adequately explain" his analysis of White, in fact finding "[a]t best, Dr. Loomis identifies changes in the shape of White's engagement members in response to temperature or compressive forces" and that "[o]n their face, such changes are incompatible with a permanent curve." (A27-28).

The PTAB also found Dr. Loomis' analysis inadequate to establish that Ostrovsky provides a permanent curve. The PTAB first found, as noted above, that Ostrovsky described a "flexible anchoring strut 202" (A30) made with "elastic materials" (A32). It then sought to determine if Dr. Loomis established that this flexible, elastic strut nevertheless had a permanent

curve. The Board concluded that he had not, noting that "[a]lthough Ostrovsky discloses the use of '*elastic* materials' . . ., Dr. Loomis fails to explain how the reference teaches the generation of a permanent curve." (A32) (Emphasis in original). *See Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 856, 102 S. Ct. 2182, 72 L. Ed. 2d 606 (1982) ("Determining the weight and credibility of the evidence is the special province of the trier of fact"). The PTAB further noted "Dr. Loomis's failure to address the forces acting on any part of an Ostrovsky device alleged to teach or disclose a permanent curve" which could establish that the *flexible* strut, made of *elastic* material nevertheless did not deform or change curvature in normal use. (A32). The PTAB therefore correctly found "the evidence of record insufficient to demonstrate that Ostrovsky maintains a permanent curve as defined herein." (A32).

Medtronic attacks the PTAB's analysis on a variety of grounds, none of which are persuasive.

### 2. MEDTRONIC'S RELIANCE ON FIGURES 33-35 OF OSTROVSKY IS MISPLACED

At pages 20 and 22 of their Principal Brief Medtronic argues that the PTAB did not analyze Figs 33-34 of Ostrovsky or appreciate that it has permanent curve. (DI-19, pp. 20, 22).

To the contrary, PTAB found that in Figure 33 "Ostrovsky's filter includes a flexible anchoring strut 202 with end 206" (A30). The PTAB further noted that: "Dr. Loomis asserts that Ostrovsky 'discloses a curve hook with a curve and materials that would maintain a permanent curve.'" (A31). However, the PTAB then properly pointed out that "Ostrovsky discloses the use of 'elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys.'" (A32). *See Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997)("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness").

And if the strut is a *flexible* strut made of *elastic materials*, there is no reason to conclude that it has "a preset curve that *maintains a fixed arc* throughout normal use regardless of what configuration the device is in." (A11)(Emphasis added). The crux of Medtronic's argument is that the strut 202 *must* have a permanent curve because Figures 33-35 do not illustrate the curvature of the hook changing. However, this is insufficient. Patent drawings are *static* figures drawn to illustrate particular features; it is necessary to consider what the various Figures of Ostrovsky are intended to show. Figures 32-35 are illustrating the use of the retraction member 208 to remove the filter from the vein. (A295, 10:30-56). These Figures are not

described as illustrating the performance of the flexible struts 202 while deployed in the vein. However, Ostrovsky does have Figures that describe the performance of the flexible struts in the vein: "FIGS. 22A-22E illustrate the *deflection* and retraction of a flexible anchor [62]"(A294, 8:30-56)(emphasis added); and those Figures clearly show the struts 62, 66 changing curvature while deployed. Ostrovsky goes on to explain that "struts 162 will *deform* generally as shown in FIGS. 22A-22E" (A295, 9:43-44)(emphasis added). Since the struts 202, like the struts 62, 162, are described as "flexible struts" and made of "elastic materials", there is no reason to conclude that they will perform differently. (A248-251, 389-390)

At pages 27-30 of their Principal Brief, Medtronic argues that Figures 29-35 do not depict the curve of strut 206 changing curvature (DI-19, pp. 27-30). This is true, but insufficient to establish a permanent curve. Again, Figures 29-35 are static representations which illustrate specific features and thus must be read in the context of the overall Ostrovsky reference which unequivocally describes struts 202, 206 of Figures 29-35 as "flexible struts," just like struts 62, 66, 162, 166. While it is true that Figures 29-35 illustrate static snap shots of the struts deployed in a vein and do not depict the curvature of the struts changing, the same is true of Figures 11-14 with regard to flexible struts 62, 66 and of Figures 20-21 of flexible struts 162,

166. None of these Figures is intended to depict the performance of the flexible struts in vivo. Rather, as noted above, it is Figures 22A-E of Ostrovsky that describe the performance of the flexible struts 62 and 162 in the vein: "FIGS. 22A-22E illustrate the *deflection*" of a "flexible anchor [62];" "struts 162 will *deform* generally as shown in FIGS. 22A-22E" (A294, 8:30-56, A295, 9:43-44) (Emphasis added). As noted above, since the struts 202, like the struts 62, 66, 162, 166 are described as "flexible struts" and made of "elastic materials", there is no reason to conclude that they will perform differently. (A248-251, 389-390).

At page 30 of its Principal Brief, Medtronic argues that Lifeport did not address Figures 33-35 in its IPR Response or allege that the curves in these figures are not identical. (DI-19, p. 30). Medtronic omits the fact that its Petition did not rely on Figures 33-35 of Ostrovsky to support its contention that the claims were obvious over White in view of Ostrovsky, but instead relied upon "elongated member" or "protrusions" 52 (Figure 3) and "protrusions" or "hooks" 166 (Figure 24). (A94, A97, A99). After Medtronic switched tactics in its Reply, and instead relied upon Figures 33-35, Lifeport addressed this embodiment at oral argument, noting that the struts 202, 206 of Figures 33-35 are described as flexible, just like the struts 62, 162 (A250, ll. 17-21), that they can be made of the same material, and

that: "merely from looking at Figure 33, 34 and 35, those figures are not intending to show you how the ends of the strut deform. So there's no reason to think that they don't deform just like as shown in Figures 22A to 22E which were the figures that were described in the patent as trying to show the flexibility of these struts." (A250, line 25 to A251, line 4).

At pages 31-33 of its Principal Brief, Medtronic alleges that the curve of Figures 33-35 are same as the '662 patent's Figures 2-3 and therefore must be permanent (DI-19, pp. 31-33). There are several problems with this argument.

First, Lifeport does not allege that Figures 33-35 *depict* a change in curvature of flexible struts 202, 206. Figures 33-35 are *static* illustrations that are described as depicting the use of the retraction member 208 to remove the filter from the vein. (A295, 10:30-56). These Figures are not intended to depict the performance of the flexible struts while deployed in the vein. The *only Figure* in Ostrovsky that is described as illustrating the performance of the flexible struts in the vein is "FIGS. 22A-22E [which] illustrate the deflection . . . of a flexible anchor" (A294, 8:30-56 (struts 62, 66), A295, 9:43-44 (struts 162, 166 *deform* as shown in Fig. 22A-E)), and those Figures clearly show that the flexible struts change curvature. As noted above, since the struts 202, like the struts 62, 162, are described as

"flexible struts" and made of "elastic materials," there is no reason to conclude that they will perform differently. (A248-251, 389-390).

The fact that Figures 33-35 do not establish that the curve of strut 202, 206 is permanent can also be seen by looking at the Figures illustrating flexible struts 62, 162. In particular, Figures 11-14 and 20-21 depict the removal of the filter with struts 62 and 162 from the vein and like Figures 33-35, no change in curvature is illustrated. Yet, Figures 22A-E and its accompanying discussion expressly describe and show that the struts 62, 66, 162, 166 do change curvature while deployed (A294, 8:30-56, A295, 9:43-44). Again, since the struts 202, like the struts 62, 162, are described as "flexible struts" and made of "elastic materials," there is no reason to conclude that they will perform differently.

Second, Medtronic's comparison of the Figures of the '662 patent to the Figures 33-35 of Ostrovsky is misplaced because it *ignores* the corresponding descriptions in the specifications. As noted above, the struts 202 of Figures 33-35 of Ostrovsky are described as "flexible" and made of "elastic" materials. In sharp contrast, the '662 patent expressly states that the hook 20 can be "permanently deformed," that it can be "compressed into alignment with the frame 22 without losing the preset curve" (A276, 6:7-11), and that is can be "permanently deformed . . . by heat setting" (A276, 6:1-2).

Further, as the PTAB properly pointed out, such a myopic focus on Figures 2-3 of the '662 patent is misplaced because "the permissive language of the Specification that hook 20 'may be permanently-deformed into the curved configuration by heat setting the material,' indicates that those embodiments may fall outside the claims ultimately issued." (A27 (citations omitted)).

### 3. AFTER FINDING THE INTRINSIC EVIDENCE LACKING, THE PTAB PROPERLY WEIGHED THE EXTRINSIC EVIDENCE AND DID NOT REQUIRE HEAT TREATMENT OR ANY METHOD OF MANUFACTURE

At pages 20 and 33-35 of its Principal Brief, Medtronic alleges that the PTAB erred in criticizing Medtronic for failing to provide extrinsic evidence, when no extrinsic evidence is required (DI-19, pp. 20, 33-35). To the contrary, the PTAB carefully considered the intrinsic evidence, and finding it lacking turned to Medtronic's extrinsic evidence. In particular, after properly noting that the relied upon components of Ostrovsky were expressly described as "flexible" and made of "elastic materials," the PTAB looked at Medtronic's extrinsic evidence to see if it established that these flexible components nevertheless had a permanent curve, and PTAB found no such credible evidence.

At pages 20, 23, 35-37 of its Principal Brief, Medtronic alleges that PTAB improperly *required* Medtronic to prove "generation of a permanent

curve" (DI-19, p. 20) and "heat treatment" (DI-19, pp. 23, 35-37). The PTAB required no such thing. Rather, the PTAB first found that the relied upon components of Ostrovsky were expressly described as "flexible" and made of "elastic materials." (A30-32). It is in this context that they noted that "Dr. Loomis fails to explain how the reference teaches the generation of a permanent curve." (A32). In other words, Dr. Loomis does not explain how these flexible and elastic materials nevertheless have "a preset curve that *maintains a fixed arc* throughout normal use regardless of what configuration the device is in." (A11)(Emphasis added). The PTAB then noted, *as an example* of the *type* of extrinsic evidence that *might* have been proffered, but was not, the '662 patent's teaching that, through heat treatment, nitinol (one of the elastic materials referenced in Ostrovsky) can be made to have a permanent curve. (A32, citing A276, 6:1-4).

On pages 21 and 23 of their Principal Brief, Medtronic alleges that the PTAB erroneously required extrinsic evidence of in vivo forces of Ostrovsky. (DI-19, pp. 21, 23). However, the PTAB did not *require* extrinsic evidence. The PTAB found that the intrinsic evidence, which showed that the components were flexible and made of elastic material, was insufficient to show that Ostrovsky had a permanent curve. (A31-32). It then looked at the extrinsic evidence provided to see if it could cure this

deficiency. It was in finding the extrinsic evidence insufficient to cure the deficiencies in the *intrinsic evidence* that the PTAB noted that Loomis provided no analysis of the in vivo forces despite the fact that Ostrovsky shows that the *flexible* struts 206 made of *elastic materials* were subject to blood flow forces and forces during removal. (A32).

### 4. MEDTRONIC'S ASSERTION THAT THE REFERENCE TO BIOCOMPATIBLE MATERIALS IN OSTROVSKY AND PLASTICS IN WHITE ESTABLISHES A PERMANENT CURVE WAS NEVER MADE TO THE PTAB AND IN ANY EVENT LACKS MERIT

At pages 38-40 of their Principal Brief, Medtronic argues that "the combination of White and Ostrovsky teaches the particular material that the '662 patent identifies as a permanent curve." (DI-19, pp. 38-40). In particular, Medtronic asserts that Ostrovsky states the struts 202 can be made of "biocompatible material" (*Id.*, at 39), and that White "teaches that other than nitinol, other biocompatible materials 'may also be appropriate for use in the manufacture of engagement members, including plastic materials.'" (*Id.*). Medtronic then posits that because the '662 patent identifies the possible use of "a ceramic or plastic hook" to provide a permanent curve (A276, 6:4-6, A156, A233, lines 24-25), that the *flexible*

*struts* of Ostrovsky must have a permanent curve. There are a number of problems with this analysis.

First, this is an entirely new argument and it is "well-settled that, absent exceptional circumstances, a party cannot raise on appeal legal issues not raised and considered in the trial forum." *Finch v. Hughes Aircraft Co*., 926 F.2d 1574, 1576 (Fed. Cir. 1991). "This rule ensures that 'parties may have the opportunity to offer all the evidence they believe relevant to the issues . . . [and] in order that litigants may not be surprised on appeal by final decision there of issues upon which they have had no opportunity to introduce evidence.'" *The John Hopkins University v. Cellpro, Inc*., 152 F.3d 1342, 1362 (Fed. Cir. 1998), *citing Hormel v. Helvering*, 312 U.S. 552, 556, 85 L. Ed. 1037, 61 S. Ct. 719 (1941). Nowhere in its briefs filed before the PTAB or at Oral Argument did Medtronic argue that the reference to "biocompatible material" in Ostrovsky (A295, 10:9-11) provided a basis for concluding the Ostrovsky had a permanent curve, nor did Medtronic ever argue that the reference to "plastic materials" in White could somehow suggest the "biocompatible material" in Ostrovsky could be plastic. "[I]t is important that the applicant challenging a decision not be permitted to raise arguments on appeal that were not presented to the Board." *In re Watts* at 1367, *see also In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) ("Review of

an administrative decision must be made on the grounds relied on by the agency."). Accordingly Medtronic cannot argue on Appeal that the PTAB erred in failing to consider an argument that was never made. *See Sage Products., Inc. v. Devon Industries*, Inc., 126 F.3d 1420, 1426 (Fed. Cir. 1997) ("In short, this court does not 'review' that which was not presented to the district court").

Second, this argument fails on its own internal logic. Ostrovsky consistently refers to the struts 62, 66, 162, 166, 202, 206 as "flexible struts" (A293, 5:39: "flexible anchoring struts 62", A295, 9:42: "struts 162 will deform … as shown in FIGS. 22A-22E", A295, 9:62: "flexible struts 202") and notes that the "struts 202 . . . may be formed from nitinol, stainless steel, or other biocompatible materials." (A295, 10:9-11). Thus, it follows that these struts would be made of *flexible* nitinol, *flexible* stainless steel, or *flexible* biocompatible materials. All of these materials can be flexible or inflexible *depending on how they are made or processed.* For example, nitinol is expressly described in the '662 patent as a material that is flexible *unless* it has been heat-treated in a specific way so that it is "permanently deformed into the curved configuration." (A276, 6:1-6). Plastics can also be either flexible or rigid depending on the type of plastic, its thickness, etc.. Medtronic's reference to the fact that the '662 patent states that a "ceramic or

plastic hook" may be used to provide a permanent curve is therefore unavailing. The struts of Ostrovsky are consistently described as *flexible*. There is simply no basis to conclude that they provide a permanent curve.

For all of the foregoing reasons, the PTAB correctly found that Ostrovsky failed to disclose a permanent curve in accordance with claims 1–5, 7–13, 15, and 16 of the '662 patent.

### G. MEDTRONIC HAS FAILED TO ESTABLISH ANY MOTIVATION TO MODIFY THE PROTRUSIONS OF WHITE IN VIEW OF OSTROVSKY

Medtronic has also failed to establish that the combination of White and Ostrovsky provides an apparent reason or motivation to modify the protrusions of White to have a permanent curve. In its Petition, Medtronic argued that Ostrovsky disclosed pointed members in the form of pointed struts, and that "a person of ordinary skill dealing with the propensity of an intraluminal device to migrate from the desired location would have been motivated to utilize the combined teachings of White and Ostrovsky ***to create a pointed end on White's engagement members ….***" (A92-93) (Emphasis added). Medtronic has never offered any other motivation.

In particular, nowhere in the record has Medtronic articulated any motivation for one of ordinary skill in the art to make any modification to the engagement members of White other than to make their ends pointed,

rather than rounded. There is no allegation in the record that Ostrovsky would lead a person or ordinary skill in the art to modify the materials used for the protrusions of White, their thicknesses, or any other characteristic other than making the rounded ends pointed. On Appeal, Medtronic does not contest the PTAB finding that the rounded engagement members of White lack a permanent curve. Accordingly, even if Ostrovsky provided a motivation to make the engagement members pointed as urged by Medtronic, the resulting combination would still lack a permanent curve. *See Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1356 (Fed. Cir. 2013) (court may affirm "on any ground that is supported by the record").

## VIII. CONCLUSION

For the foregoing reasons, this appeal should be denied.

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## IX. CERTIFICATE OF COMPLIANCE

Counsel for appellee Lifeport certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure. The brief contains 10,765 words,excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure, as computed by the word count feature of Microsoft Word.

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## CERTIFICATE OF SERVICE

I certify that on December 9, 2015, I served a copy of the foregoing document on all counsel of record for Appellant by CM/ECF.

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